

In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS

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ROBERT GIESBRECHT,	*	No. 16-1338V
	*	Special Master Christian J. Moran
Petitioner,	*	
V.	*	
	*	Filed: February 8, 2023
SECRETARY OF HEALTH	*	
AND HUMAN SERVICES,	*	Entitlement, flu, polymyalgia
	*	rheumatica (PMR), diagnosis
Respondent.	*	

* * * * *

Amy A. Senerth, Muller Brazil, LLP, Dresher, PA, for petitioner;
Christine Becer, United States Dep’t of Justice, Washington, DC, for respondent.

PUBLISHED DECISION DENYING ENTITLEMENT¹

Mr. Giesbrecht alleges an influenza (“flu”) vaccine caused him to suffer a musculoskeletal condition, known as polymyalgia rheumatica (“PMR”). The Secretary disagrees with this claim.

Both parties developed their positions by first submitting reports from experts: Dr. Eric Gershwin for Mr. Giesbrecht and Dr. Robert Lightfoot for the Secretary. Then, the parties advocated through briefs. One of the areas of dispute is whether PMR is an appropriate diagnosis for Mr. Giesbrecht. On this point, the Secretary has persuasively shown that PMR does not fit Mr. Giesbrecht’s presentation. Mr. Giesbrecht’s failure to establish with preponderant evidence that he suffers from PMR means that he cannot receive compensation. Moreover, if PMR were an appropriate diagnosis for Mr. Giesbrecht, the theory by which he

¹ The E-Government Act, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services), requires that the Court post this decision on its website. This posting will make the decision available to anyone with the internet. Pursuant to Vaccine Rule 18(b), the parties have 14 days to file a motion proposing redaction of medical information or other information described in 42 U.S.C. § 300aa-12(d)(4). Any redactions ordered by the special master will appear in the document posted on the website.

proposes a flu vaccine can cause PMR is not persuasive. This lack of persuasive evidence constitutes an independent reason for denying entitlement. Accordingly, Mr. Giesbrecht's case is dismissed.

I. Diagnostic Criteria for PMR

Mr. Giesbrecht alleges that he suffers from PMR and Dr. Gershwin supports that contention. However, the Secretary and Dr. Lightfoot disagree. To provide context for the events in Mr. Giesbrecht's medical history, the diagnostic criteria are set forth.

Dr. Gershwin and Dr. Lightfoot agree that PMR is a clinical diagnosis. Exhibit 8 at 2; Exhibit A at 6. In basic terms, PMR affects people older than 50 years and causes "aching and stiffness . . . [in] most typically the neck, the shoulders, proximal regions of the arms, hips and proximal areas of the thighs." Exhibit 8 at 2. Other diagnostic criteria include "Morning stiffness lasting more than one hour," "Rapid response to prednisone (≤ 20 mg/day)," "Absence of other diseases capable of causing the musculoskeletal symptoms," and "Erythrocyte sedimentation rate greater than 40 mm/hour." Exhibit 8, tab 14 (Carlo Salvarani, et al., "Polymyalgia Rheumatica and Giant-Cell Arteritis," 347 (4) N. Eng. J. Med. 261) (2002)) at 261 (Table 1).

According to Dr. Lightfoot, distinguishing between PMR and osteoarthritis is difficult. Exhibit A at 6. Because PMR, by definition, occurs in individuals older than 50 years, and because osteoarthritis also correlates with age, "there is a high prevalence of osteoarthritis . . . in the PMR population." *Id.* Dr. Lightfoot states that doctors "are quite frequently required to use the ESR or CRP to distinguish OA [osteoarthritis] from PMR." *Id.*

II. Events in Mr. Giesbrecht's Medical History²

A. Events before Vaccination³

Mr. Giesbrecht was born in 1948. In October 2014, he worked at Case New Holland, in Fargo, North Dakota, where he received his vaccine from an onsite nurse.

² Among the various submissions, Dr. Lightfoot's recitation of facts was the most thorough.

³ In his initial report, Dr. Gershwin summarizes Mr. Giesbrecht's "multiple medical issues" in a single paragraph in which Dr. Gershwin did not cite any evidence by exhibit number

The earliest records come from Mark Yohe, a primary care doctor, whom Mr. Giesbrecht began to see on February 8, 2012. Exhibit 2 at 8. Mr. Giesbrecht informed Dr. Yohe that he was taking, among other medications, atorvastatin (Lipitor) for control of his hyperlipidemia.⁴ Id. at 11-12. Mr. Giesbrecht's body mass index was 36.25, a score indicating obesity. Id. at 9.

Mr. Giesbrecht complained of right forearm pain, which he associated with heavy lifting during a recent move. Id. at 8. Dr. Yohe's review of systems ("ROS") included "joint pain" and "numbness." Id. at 9. On exam, Dr. Yohe determined that Mr. Giesbrecht had tenderness in the right humeral lateral epicondyle ("tennis elbow"), which Dr. Yohe injected with steroids. Id. at 8, 12.

On June 8, 2012, Dr. Yohe noted "fatigue" and "muscle weakness" among Mr. Giesbrecht's complaints. Exhibit 2 at 16.

In 2013, Mr. Giesbrecht twice reported back pain. The first occasion was on March 13, 2013, when he sought care for pain in the neck and upper back, which he attributed to having "slept wrong" two weeks previously. Exhibit 2 at 44. On exam, Dr. Yohe found Mr. Giesbrecht to have mild tenderness in the left trapezius "as well as tension and spasm." Id. at 45. Dr. Yohe prescribed a pain medication, Tramadol. Id.

A few weeks later, Mr. Giesbrecht's ROS during his annual exam indicates "complain[t]s of back pain." Id. at 57 (April 5, 2013).

Other musculoskeletal problems appear in records created in 2014. On February 10, 2014, Mr. Giesbrecht complained about left groin pain "deep into the muscles," "ongoing for several months." Id. at 89. He also reported pain in his left calf, beginning 6 years ago. Id. at 90. The impression was "thigh pain...likely muscular in nature." Id. at 91.

Mr. Giesbrecht sought treatment for "right hip discomfort [which began] about 10 days" ago with "some occasional groin discomfort" on April 21, 2014.

and page number. See Exhibit 8 at 1. Mr. Giesbrecht's recitation of relevant facts begins with his vaccination. See Pet'r's Mot. for Ruling on the Record, filed Oct. 20, 2020, at 3. The Secretary's presentation of facts from before the vaccination is contained in five sentences with cites to evidence. Resp't's Resp., filed Dec. 4, 2020, at 2.

⁴ About eight months later, Dr. Yohe stated that Mr. Giesbrecht "had a change in his lipid medication when I first saw him." Exhibit 2 at 23 (October 4, 2012). However, the details about this change are not provided.

Exhibit 2 at 96. The nurse's note indicates "it started out with soreness" and was "now [] very painful." Id. at 97. The physical exam revealed he was tender to palpation over the lateral aspect of the right hip. Id. He was given an 80 mg injection of the anti-inflammatory corticosteroid, Depomedrol. Id. at 98.

Mr. Giesbrecht continued to have problems with his back for the next few months. An MRI of his lumbar spine revealed severe degenerative disc and facet disease with spinal stenosis. Exhibit 5 at 109. Mr. Giesbrecht underwent an operation on his lumbar spine. Id. at 128 (June 24, 2014).

At a visit to Dr. Yohe on July 11, 2014, approximately 17 days post-spinal surgery, Mr. Giesbrecht reported three days of low back pain and stiff hip joints, chills and "maybe had some fevers," in addition to arthralgias. Exhibit 2 at 127-28. Dr. Yohe did not detect any abnormalities at the operation site. See id.

On September 23, 2014, Mr. Giesbrecht returned for an office visit because of recurrence of back pain on his left side for the previous two weeks. The clinical impression was "lumbar back pain on the opposite side." Id. at 130.

B. Events Starting with the Vaccination

Mr. Giesbrecht received a flu vaccination on October 31, 2014. Exhibit 1 at 1. He alleges this vaccination harmed him.

Mr. Giesbrecht saw Dr. Yohe on December 19, 2014 and complained of bilateral shoulder and hip pain with morning stiffness for the past two months. Exhibit 2 at 137-39. He associated the onset of his problems with the flu shot. Id.⁵ In a review of systems, Mr. Giesbrecht reported neck pain, joint pain, and muscle pain. Id. at 138. Dr. Yohe noted that while there was "no tenderness on palpation of shoulders or hips," there was "[p]ain noted with ROM (range of motion) to shoulders and hips." Id. at 139. Dr. Yohe's impression was "possibl[e] PMR . . . vs. arthritis." Id.

During this appointment, Dr. Yohe ordered laboratory tests, including tests for erythrocyte sedimentation rate ("ESR") and C-reactive protein ("CRP"). Id. The results showed an ESR of 38 mm/hour and CRP at 1.11 mg/dL. Id. at 135-36. According to Dr. Lightfoot, an ESR of this level is not abnormal for a person of Mr. Giesbrecht's age. Exhibit A at 6. Dr. Yohe prescribed 20 mg per day of

⁵ If Mr. Giesbrecht's recitation of "two months," is accurate to the day, then his problems started on October 19, 2014, which is before he was vaccinated.

prednisone. Exhibit 2 at 140. Dr. Lightfoot describes this step as “the preferred initial treatment of PMR.” Exhibit A at 5.

After the laboratory tests had been returned and after Mr. Giesbrecht started prednisone, he returned to Dr. Yohe on January 7, 2015. Exhibit 2 at 140-42. Mr. Giesbrecht reported that he continued to have pain in his hips and shoulders but that the pain has improved primarily in the hip area. Id. at 140. Dr. Yohe stated that “It’s possible he has developed PMR.” Id. at 141.

Mr. Giesbrecht telephoned Dr. Yohe with various questions on January 23, 2015. Exhibit 2 at 145. Dr. Yohe responded by stating that Mr. Giesbrecht’s diagnosis “might be polymyalgia rheumatica.” Id. Dr. Yohe suggested tapering the dose of prednisone. Id. Although Mr. Giesbrecht apparently also was associating his signs and symptoms with the flu shot, Dr. Yohe’s written note does not address this specific point. Id.

A follow-up appointment with Dr. Yohe occurred on March 3, 2015. Id. at 146-48. The history of present illness begins: “Robert presents today for follow up of his polymyalgia.” Id. at 146. Mr. Giesbrecht reported that he was experiencing joint pains, primarily in his shoulders and hips, when he reduced the amount of prednisone from 15 mg to 10 mg. Id. Dr. Yohe’s list of “Current Problems (verified)” includes 20 conditions with various diagnostic codes, including “Muscle Pain” and “Pain in Joint, Multiple Sites.” Id. This list does not include polymyalgia rheumatica. Dr. Yohe’s impressions included: “Polymyalgia rheumatica.” Id. at 148. He increased the dose of prednisone to 15 mg and recommended a follow-up in three more months for additional lab work. Id.

Following the March 3, 2015 appointment, “Polymyalgia Rheumatica” appears among the “Current Problems (verified)” in Dr. Yohe’s reports. See, e.g., Exhibit 2 at 153 (Mar. 11, 2015). The lab test that Dr. Yohe requested showed that Mr. Giesbrecht’s ESR was normal. Exhibit 3 at 43 (June 1, 2015). According to Dr. Lightfoot, “Several repeat ESR and CRP values were obtained through this course and were in the normal range for the general population,” Exhibit A at 5, and neither Dr. Gershwin nor Mr. Giesbrecht has contested Dr. Lightfoot’s account.

Medical records created after March 3, 2015 reflect an effort to taper prednisone, but Mr. Giesbrecht was not able to tolerate a dose below 10 mg. Exhibit 3 at 7, 9. At the same time, Dr. Yohe was concerned about how prednisone was complicating Mr. Giesbrecht’s diabetes. See Exhibit A at 5. In

any event, Mr. Giesbrecht does not advance any medical records created after May 5, 2017. Pet'r's Mot. at 5; see also Resp't's Resp. at 3 (ending with May 5, 2017).

III. Procedural History

Mr. Giesbrecht alleged the October 31, 2014 flu vaccination caused him to suffer polymyalgia rheumatica. Pet., filed Oct. 13, 2016. Over the next ten months, Mr. Giesbrecht submitted various medical records. See Pet'r's Statement of Completion, filed June 19, 2017.

The Secretary reviewed this material and recommended that compensation be denied. Resp't's Rep., filed Sep. 5, 2017. Specifically, the Secretary maintained that Mr. Giesbrecht "does not allege a Table injury, and the records do not support that any injury listed on the Table occurred." Id. at 4. Additionally, the Secretary stated that Mr. Giesbrecht did not prove that the flu vaccine caused his PMR and that "[n]one of the treating physicians provided an opinion that the flu vaccine had a causal role in petitioner's illness." Id. at 5.

After the Secretary's report, the parties obtained reports from experts. Each party ultimately submitted three expert reports. Dr. Gershwin's reports are Exhibit 8 (filed Jan. 3, 2018), Exhibit 11 (filed Sep. 14, 2018), and Exhibit 12 (filed May 20, 2019). Dr. Lightfoot's reports are Exhibit A (filed Mar. 16, 2018), Exhibit F (filed Dec. 13, 2018), and Exhibit J (filed Aug. 19, 2019). The parties periodically filed medical articles on which their expert relied.

The special master to whom the case was then assigned questioned whether Mr. Giesbrecht distinguished his case from other polymyalgia rheumatica cases in which the special master had found the petitioner was not entitled to compensation. Order, issued Mar. 6, 2020. In response, Mr. Giesbrecht maintained that Dr. Gershwin was presenting a different opinion. Pet'r's Mem., filed June 4, 2020.

Mr. Giesbrecht requested a ruling in his favor based upon the record. Pet'r's Mot., filed Oct. 20, 2020. Mr. Giesbrecht's double-spaced motion consists of sections on procedural history (2 pages), facts (3 pages), legal standards (one-half page), and analysis (2 pages). Mr. Giesbrecht's motion does not cite any medical articles.

Although the Secretary agreed with a disposition on the papers, the Secretary maintained that Mr. Giesbrecht had not demonstrated that he was entitled to compensation. Resp't's Resp., filed Dec. 4, 2020. The Secretary's response consists of facts (2 pages), legal standards (3.5 pages), and analysis (3.5 pages). The Secretary also does not cite any medical articles.

Mr. Giesbrecht submitted a six-page reply on January 14, 2021. He again requested a ruling in favor of entitlement.

The case was transferred to the undersigned. In a status conference, the parties confirmed that they wished for the case to be decided in its present state. See order, issued Feb. 28, 2022. This makes the case ready for adjudication.

IV. Standards for Adjudication

A petitioner is required to establish his case by a preponderance of the evidence. 42 U.S.C. § 300aa-13(1)(a). The preponderance of the evidence standard requires a “trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact’s existence.” Moberly v. Sec’y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted). Proof of medical certainty is not required. Bunting v. Sec’y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Distinguishing between “preponderant evidence” and “medical certainty” is important because a special master should not impose an evidentiary burden that is too high. Andreu v. Sec’y of Health & Hum. Servs., 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing a special master’s decision that petitioners were not entitled to compensation); see also Lampe v. Sec’y of Health & Hum. Servs., 219 F.3d 1357 (Fed. Cir. 2000); Hodges v. Sec’y of Health & Hum. Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (disagreeing with the dissenting judge’s contention that the special master confused preponderance of the evidence with medical certainty).

When pursuing an off-Table claim, the petitioner bears a burden “to show by preponderant evidence that the vaccination brought about [the vaccinee’s] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.” Althen v. Sec’y of Health & Hum. Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

Furthermore, as a threshold matter, a petitioner must establish he suffers from the condition for which he seeks compensation. Broekelschen v. Sec’y of Health & Hum. Servs., 618 F.3d 1339, 1346 (Fed. Cir. 2010). When a petitioner fails to establish his diagnosis, there is no need for an analysis pursuant to Althen, 418 F.3d at 1278. See Lombardi v. Sec’y of Health & Hum. Servs., 656 F.3d 1343, 1353 (Fed. Cir. 2011).

V. Analysis

Two independent reasons support a denial of compensation. First, preponderant evidence does not show that Mr. Giesbrecht suffers from polymyalgia rheumatica. Second, even if PMR were an appropriate diagnosis, the theory by which the flu vaccine could have caused this problem in Mr. Giesbrecht is not persuasive.

A. Diagnosis

Mr. Giesbrecht's contention that he suffers from polymyalgia rheumatica starts with a presumptively reliable foundation in that Dr. Yohe, his primary treating doctor, stated that he suffers from polymyalgia rheumatica. Exhibit 2 at 153 (Mar. 11, 2015); see also Pet'r's Mot. at 6. However, a medical record's statement of "diagnosis . . . shall not be binding on the special master." 42 U.S.C. § 300aa-13(b)(1). In this case, a critical evaluation of the history of treatment with Dr. Yohe and an analysis of the reports from Dr. Gershwin and Dr. Lightfoot undermine the usual persuasive value given to the report of a treater regarding diagnosis.

Mr. Giesbrecht's progression of appointments with Dr. Yohe do not explain the basis for Dr. Yohe's statement of PMR. Before the vaccination, Mr. Giesbrecht had a history of musculoskeletal complaints starting with the initial visit with Dr. Yohe. See Exhibit 2 at 9 ("joint pain" on February 8, 2012), 16 ("muscle weakness" on June 8, 2012), 44 (upper back pain in the context of possibly sleeping wrong on March 13, 2013), 57 ("complains of back pain" on April 5, 2013), 96 ("right hip discomfort" on April 21, 2014), 127-28 (stiff hip joints and arthralgias on July 11, 2014). Dr. Yohe appears not to have written in a medical record that any of these symptoms were manifestations of either PMR or osteoarthritis.

After the flu vaccination on October 31, 2014, Mr. Giesbrecht reported that he was experiencing bilateral shoulder and hip pain with morning stiffness for the past two months. Exhibit 2 at 137-39 (Dec. 19, 2014). Dr. Yohe's impression was "possibl[e] PMR . . . vs. arthritis." Id. at 139.

An ensuing laboratory test showed that Mr. Giesbrecht's ESR was 38 mm/hour. Exhibit 2 at 136. Whether this value is normal is discussed more extensively below.

In the follow-up appointment, Mr. Giesbrecht reported that he continued to have pain in his hips and shoulders but that the pain has improved. Id. at 140 (Jan.

7, 2015). Dr. Yohe stated that “It’s possible he has developed PMR.” Id. at 141. Through an exchange of telephone messages, Dr. Yohe expressed a similar opinion that Mr. Giesbrecht’s diagnosis “might be polymyalgia rheumatica.” Id. at 145 (Jan. 23, 2015).

In the March 3, 2015 report, “polymyalgia” appears as part of the history of present illness, which comes from the patient. Exhibit 2 at 146. The term does not appear among the “Current Problems (verified).” However, in this report, Dr. Yohe’s impressions included: “Polymyalgia rheumatica.” Id. at 148.

The record does not contain any explanation for a shift in Dr. Yohe’s assessment. Before March 3, 2015, Dr. Yohe seemed to have some doubt about whether Mr. Giesbrecht was suffering from polymyalgia rheumatica. In the December 19, 2014 medical record, Dr. Yohe stated that polymyalgia rheumatica and arthritis were possible. Exhibit 2 at 139. Dr. Yohe used similar terminology in the two medical records from January 2015. In one report, Dr. Yohe said, “It’s possible he has developed PMR.” Id. at 141. In the other report, Dr. Yohe stated the diagnosis “might be polymyalgia rheumatica.” Id. at 145. This terminology suggests a degree of uncertainty in Dr. Yohe’s diagnosis.

Moreover, Dr. Lightfoot has set forth a number of points that question whether PMR is an appropriate diagnosis. Most importantly, Dr. Lightfoot has indicated that osteoarthritis could fit Mr. Giesbrecht’s presentation: “It is highly likely that petitioner has degenerative arthritis (osteoarthritis (OA)) in both his lumbar spine and his cervical spine, given his pre-vaccinal problems with neck pain and his clearly osteoarthritic lumbar spine.” Exhibit A at 6. Dr. Gershwin agreed: “It is certainly likely that Mr. Giesbrecht, by virtue of his age, has osteoarthritis.” Exhibit 11 at 1; accord Exhibit 12 at 1 (Dr. Gershwin acknowledging that Mr. Giesbrecht’s July 11, 2014 presentation is consistent with “his previous history of . . . osteoarthritis”).

As to osteoarthritis, Mr. Giesbrecht’s argument was not persuasive. He contested: “Petitioner does not admit or deny that he has osteoarthritis, as the diseases are not mutually exclusive.” Pet’r’s Reply at 4. This argument, which was put forward in a reply brief, overlooks the diagnostic criteria for PMR. An article from the New England Journal of Medicine on which Dr. Gershwin relied stated the diagnostic criteria for polymyalgia rheumatica includes: “Absence of other diseases capable of causing the musculoskeletal symptoms.” Exhibit 8, tab 14 (Salvarani) at 261 (Table 1). Mr. Giesbrecht’s position of neither admitting nor denying osteoarthritis is also inconsistent with his own expert’s statement that Mr. Giesbrecht has osteoarthritis.

A way to distinguish polymyalgia rheumatica from osteoarthritis is to test the erythrocyte sedimentation rate. Exhibit A at 6. When Mr. Giesbrecht's ESR was first tested, the result was reported as elevated beyond the normal range, which was 0-15. Exhibit 2 at 136. In Dr. Lightfoot's initial report, Dr. Lightfoot explained that the expected ranges change as people age. Exhibit A at 6, citing exhibit C (A Miller, et al., "Simple rule for calculating normal erythrocyte sedimentation rate," 286 Brit. Med. J. 266 (1983)). In his responsive reports, Dr. Gershwin did not contest that age affects normal ESR rates. See Exhibits 11&12. This absence of rebuttal contributes to the persuasiveness of Dr. Lightfoot's opinion that the December 19, 2014 lab test is not helpful for diagnosis. See Exhibit J at 3.

Dr. Lightfoot also opined that Mr. Giesbrecht might suffer from a statin myopathy. Exhibit A at 7. Dr. Lightfoot went so far as to describe a statin myopathy as "very likely." Id. at 8. While a statin myopathy seems to be a possibility, the only way to test for a statin myopathy, stopping the medication, has not been done in Mr. Giesbrecht's case. See id. at 7. Without more support in the medical records, the evidence supporting an alternative diagnosis of statin myopathy does not exceed the "more likely than not" standard. Nevertheless, the Secretary does not bear the burden of establishing another alternative diagnosis.⁶ See Lombardi v. Sec'y of Health & Hum. Servs., 656 F.3d 1343 (Fed. Cir. 2011).

The responsibility for establishing that a vaccinee suffers from a condition allegedly caused by a vaccine falls to the petitioner. In this case, for the reasons explained above, Mr. Giesbrecht has not met this burden.⁷

B. Causation Theory

When a petitioner fails to establish his diagnosis, there is no need for an analysis pursuant to Althen, 418 F.3d at 1278. See Lombardi, 656 F.3d at 1353. However, for sake of completeness, one Althen prong is discussed.

The first Althen prong requires the petitioner to provide a "sound and reliable" medical theory demonstrating that the vaccine can cause the alleged

⁶ "Another" alternative diagnosis refers to Dr. Gershwin's and Dr. Lightfoot's agreement that Mr. Giesbrecht suffers from osteoarthritis.

⁷ To some extent, the question of diagnosis relates to the question of onset. If polymyalgia rheumatica were an appropriate diagnosis, then the onset of the condition could have been before the vaccination because on July 11, 2014, Mr. Giesbrecht reported problems in his hips. Exhibit 2 at 127.

injury. Boatmon v. Sec'y of Health & Hum. Servs., 941 F.3d 1351, 1359 (Fed. Cir. 2019) (quoting Knudsen v. Sec'y of Health & Hum. Servs., 35 F.3d 543, 548 (Fed. Cir. 1994)). The petitioner must also offer “a reputable medical or scientific explanation that pertains specifically to [his] case.” Moberly, 592 F.3d at 1322.

Dr. Gershwin acknowledged in his report that “The mechanism of polymyalgia rheumatica still remains enigmatic.” Exhibit 8 at 2. In the conclusion to this report, Dr. Gershwin mentions that polymyalgia rheumatica is an autoimmune disease. Id. at 4. He did not provide any authority for this proposition, although Dr. Gershwin had earlier stated that polymyalgia rheumatica is similar to a different condition, temporal arteritis. Id. at 2.

Dr. Lightfoot states a leading textbook on rheumatology does not describe PMR as an autoimmune condition. Exhibit F at 4.⁸ Without some basic evidence showing that PMR occurs via an autoimmune process, a causal link to the flu vaccine seems difficult.

Mr. Giesbrecht described the theory he was advancing as “The mechanism of the PMR would be the generation of an innate immune response involving cytokine production.” Pet’r’s Br. at 7, quoting Exhibit 8 at 4. The advocacy for this theory is underwhelming. As pointed out previously, Mr. Giesbrecht’s presentation of his theory was approximately one page, consisting largely of block quotes extracted from Dr. Gershwin’s first report. Mr. Giesbrecht did not discuss any medical articles that Dr. Gershwin cited.

In any event, special masters have often not found a theory based upon cytokines persuasive. Langley v. Sec'y of Health & Hum. Servs., No. 17-837V, 2022 WL 897959, at *15 (Fed. Cl. Spec. Mstr. Mar. 3, 2022) (rejecting theory that cytokines can cause an anxiety disorder and citing cases); A.S. via Svagdis v. Sec'y of Health & Hum. Servs., No. 15-520V, 2022 WL 1077884, at *37-41 (Fed. Cl. Spec. Mstr. Feb. 17, 2022) (rejecting theory presented by Dr. Gershwin and others that cytokines can worsen a mitochondrial disorder and citing cases); Downing-Powers v. Sec'y of Health & Hum. Servs., No. 15-1043V, 2020 WL 4197303, at *12-15 (Fed. Cl. Spec. Mstr. June 2, 2020) (rejecting, largely due to Boatmon v. Sec'y of Health & Hum. Servs., 941 F.3d 1351 (Fed. Cir. 2019), a theory that cytokines lead to the sudden unexpected death in an infant); Castanega v. Sec'y of Health & Hum. Servs., No. 15-1066V, 2020 WL 3833076, at *23-27 (Fed. Cl. Spec. Mstr. May 18, 2020) (citing cases and rejecting theory that

⁸ The Secretary did not file the relevant chapter as an exhibit.

cytokines cause pediatric acute-onset neuropsychiatric syndrome), mot. for rev. denied, 152 Fed. Cl. 576, 584-87 (2020);⁹ Landis v. Sec'y of Health & Hum. Servs., No. 15-1562V, 2019 WL 7844617, at *11 (Fed. Cl. Spec. Mstr. Aug. 20, 2019) (citing cases and rejecting theory that cytokines cause osteoarthritis); McKown v. Sec'y of Health & Hum. Servs., No. 15-1451V, 2019 WL 4072113, at *50 (Fed. Cl. Spec. Mstr. July 15, 2019) (noting the “fact that cytokine upregulation is promoted by vaccination – a medically reliable assertion standing alone – does not mean that this cytokine increase is definitionally *harmful*” and rejecting the theory that cytokines cause eczema); Baron v. Sec'y of Health & Hum. Servs., No. 14-341V, 2019 WL 2273484, at *18-19 (Fed. Cl. Spec. Mstr. Mar. 18, 2019) (rejecting theory that cytokines cause anti-NMDA encephalitis); Nunez v. Sec'y of Health & Hum. Servs., No. 14-863V, 2019 WL 2462667, at *40-41 (Fed. Cl. Spec. Mstr. Mar. 29, 2019) (rejecting theory that cytokines cause sudden infant deaths), mot. for rev. denied, 144 Fed. Cl. 540, 547 (2019), aff'd, 825 F. App'x 816 (Fed. Cir. 2020). These cases suggest that additional evidentiary development, which neither party requested, would be unlikely to cure the gaps in Dr. Gershwin’s opinion.

Finally, the result in this case---a finding that a petitioner has not established that a vaccine can cause polymyalgia rheumatica---is consistent with the results in other cases. Twice in reasoned decisions, a special master has determined petitioners failed to meet their burden of showing how a vaccine can cause polymyalgia rheumatica. See Suliman v. Sec'y of Health & Hum. Servs., No. 13-993V, 2018 WL 6803697, at * 25-28 (Fed. Cl. Spec. Mstr. Nov. 27, 2018) (Tdap vaccine); C.P. v. Sec'y of Health & Hum. Servs., No. 14-917V, 2019 WL 5483621, at *22-28 (Fed. Cl. Spec. Mstr. Aug. 21, 2019) (flu vaccine). On four other occasions, petitioners failed to present minimally persuasive evidence and sought dismissal of their cases. See Gauthier v. Sec'y of Health & Hum. Servs., No. 18-753V, 2021 WL 5754976 (Fed. Cl. Spec. Mstr. Oct. 5, 2021) (flu vaccine); Godek v. Sec'y of Health & Hum. Servs., No. 19-106V, 2021 WL 1851389 (Fed. Cl. Spec. Mstr. Apr. 15, 2021) (Tdap vaccine); Discher v. Sec'y of Health & Hum.

⁹ In denying the motion for review, the Court suggested that five previous cases involving theories based on cytokines would not provide a basis for rejecting a similar theory in another case. 152 Fed. Cl. at 585. However, the Court did not acknowledge that Congress expected special masters to use their “accumulated expertise.” Whitecotton v. Sec'y of Health & Human Servs., 81 F.3d 1099, 1104 (Fed. Cir. 1996) (quoting Hodges v. Sec'y of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993)). This accumulated expertise teaches that theories based upon cytokines tend to be similar and similarly deficient. In any event, Dr. Gershwin’s theory regarding cytokines is not accepted in this case because Mr. Giesbrecht has not demonstrated its persuasiveness.

Servs., No. 18-777V, 2019 WL 6701681 (Fed. Cl. Spec. Mstr. Nov. 12, 2019) (flu vaccine); Johnson v. Sec'y of Health & Hum. Servs., No. 14-931V, 2019 WL 1992631 (Fed. Cl. Spec. Mstr. Apr. 11, 2019) (flu vaccine).

These previous cases support, but do not dictate, the outcome here. While the evidence in Mr. Giesbrecht's case differs in some ways from those other cases, the evidence here remains unpersuasive. Accordingly, Mr. Giesbrecht has not met his burden of proof regarding Althen prong one.

VI. A Hearing Is Not Required

Special masters possess discretion to decide whether an evidentiary hearing will be held. 42 U.S.C. § 300aa-12(d)(3)(B)(v) (promulgated as Vaccine Rule 8(c) & (d)), which was cited by the Federal Circuit in Kreizenbeck v. Sec'y of Health & Hum. Servs., 945 F.3d 1362, 1365 (Fed. Cir. 2018).

Mr. Giesbrecht has had a fair and full opportunity to present his case. After Dr. Gershwin presented his initial opinion, Dr. Lightfoot critiqued it, persuasively pointing out gaps in Dr. Gershwin's report. Mr. Giesbrecht then presented a rebuttal opinion from Dr. Gershwin, which Dr. Lightfoot again critiqued. Mr. Giesbrecht's efforts to address any deficiencies in Dr. Gershwin's reports during the briefing process were unpersuasive. Ultimately, Mr. Giesbrecht was unable to establish that polymyalgia rheumatica was an appropriate diagnosis and Mr. Giesbrecht was unable to offer a persuasive theory by which a flu vaccine can cause polymyalgia rheumatica. Therefore, a hearing is not needed to resolve these issues.

VII. Conclusion

Mr. Giesbrecht alleged a flu vaccine caused him to suffer polymyalgia rheumatica. He has not established with preponderant evidence two elements of his case: 1) polymyalgia rheumatica is an appropriate diagnosis and 2) a flu vaccine can cause this condition. Accordingly, Mr. Giesbrecht is not entitled to compensation.

The Clerk's Office is instructed to enter judgment in accordance with this decision unless a motion for review is filed. Information about filing a motion for review, including the deadline, can be found in the Vaccine Rules, available through the Court's website.

IT IS SO ORDERED.

s/Christian J. Moran
Christian J. Moran
Special Master